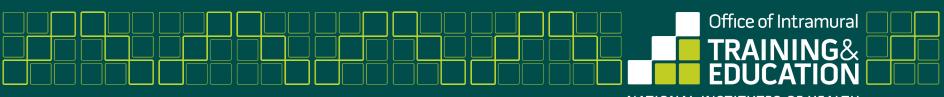
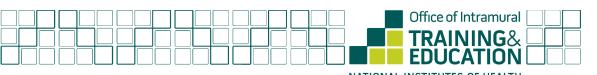
# **Grant Writing 101**

Dr. Sharon L. Milgram, Director NIH OITE milgrams@od.nih.gov

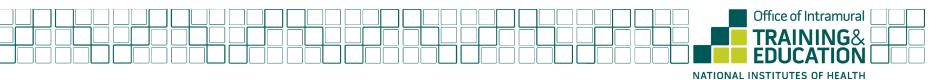


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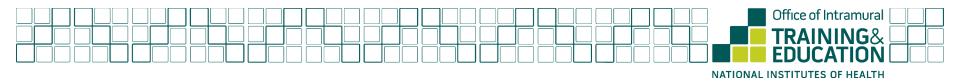
### Take Home Message

You will decrease your stress level and have more time to focus on science if you take the time to understand the grant writing process -- from first idea to final outcome



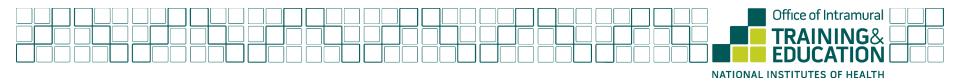
### What We Will Cover Today

- Part I: Understanding the process
  - Finding funding opportunities
  - Understanding the NIH
  - Peer review
- Part II: Writing your application
  - Components of research and training grants
  - Developing your aims and strategies for presenting your ideas
  - Responding to critiques

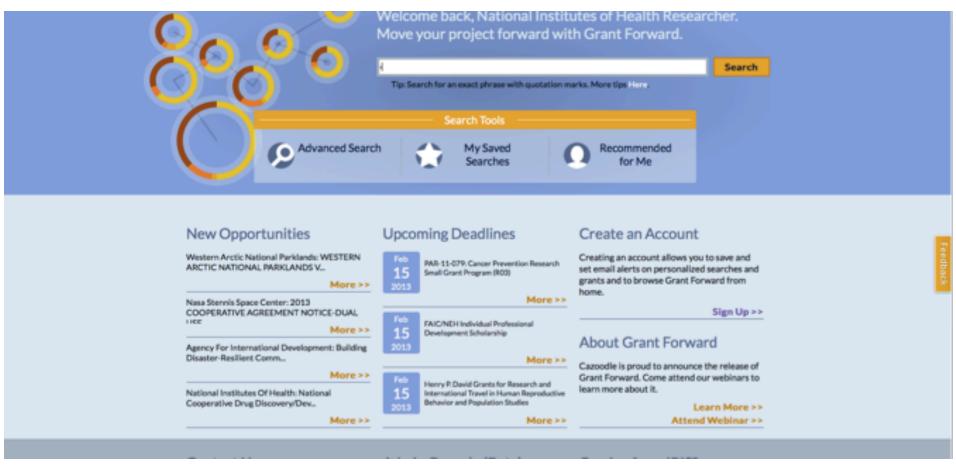


### What We Will NOT Cover

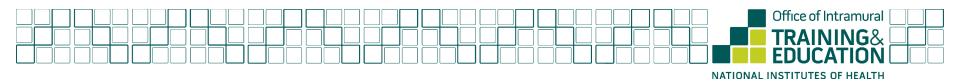
Advice specific to you and your personal situation



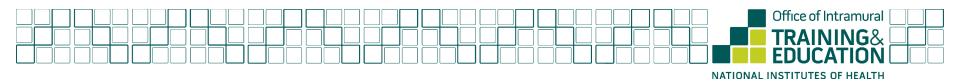
### An Important Resource



www.grantforward.com



# Understanding the NIH



## Warnings and Disclaimers Up-Front

- Each NIH Institute has a different mission and a different set of policies and procedures. Grant mechanisms, rules, and support for various funding mechanisms may differ
- Everyone has their own opinion ask many knowledgeable people and spend A LOT of time on the OER website



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### An Overview of the Process





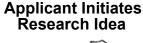




### **National Institutes** of Health

















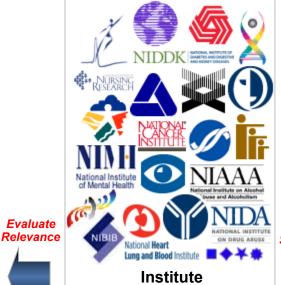






affairs.

**Evaluate** 





### Assign to Institute and Study Section





#### **Peer Review**



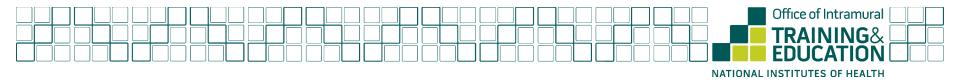
1st NIH Study Section 1946





### **Explore Relevant ICs**

- Your goal is to find the NIH IC(s) most likely to care about what you do
- Links to IC web pages at <u>www.nih.gov/icd/</u>
- Following FUNDING tab to find information on specific research programs
  - Read about general areas of emphasis
  - Find Funding Opportunity Announcements (FOAs)
  - Find relevant contacts and reach out by email
- Remember: Your research may be of interest to more than one Institute



### **Understand Extramural**

HOME

ABOUT GRANTS

FUNDING

FORMS & DEADLINES

**GRANTS POLICY** 

**NEWS & EVENTS** 

ABOUT OER

NIH HOME

### **GRANTS & FUNDING**

#### **About Grants**

Grants Process Overview Grant Application Basics

Types of Grant Programs

How to Apply

Peer Review Process

Award Management

Foreign Grants

Information

Funding Strategies

#### **Electronic Grants**

Electronic Research Admin (eRA)

eRA Commons

Applying Electronically



#### **FUNDING**

Search NIH Guide for Grants and Contracts

Search

Funding Opportunities & Notices
Unsolicited Applications (Parent Announcements)



### Rock Talk

NEW Two Years of Rock Talking!

NEW Revisiting the Relationship Between Paylines and Success Rates

FY2012 By The Numbers: Success Rates, Applications, Investigators, and Awards

#### **Latest News and Events**

PHS2590 Now Available with My
NCBI

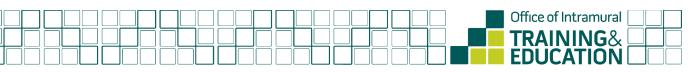
Public Access Compliance Monitor: New Web-Based Tool Available

### www.grants.nih.gov



# The Center For Scientific Review www.csr.nih.gov

- Central receipt point for all NIH grant applications
- Receipt and Referral Branch is responsible for directing your application to the appropriate study section and Institute for funding consideration
- Also manages ~200 Study Sections
  - Some grants are reviewed by study sections organized by an NIH Institute



### Important Extramural Contacts

- Program Officer (PO)
  - Institute Staff who manage a portfolio of awarded grants in a particular scientific discipline or funding area
  - Speaks with potential applicants about eligibility, fit with the IC, etc.
  - Monitors scientific progress made on grant
- Scientific Review Officer (SRO)
  - CSR or Institute Staff
  - Organizes and manages study section
  - Liaison between applicant and reviewers
  - Prepares summary statements
- Grants Management Officer



### Main Types of NIH Grants

- Research Training & Fellowships (T & F series)
- Career Development Awards (K series)
- Research grants (R series)
- Program project/center grants (P series)
- Trans-NIH Programs (Diversity supplements, GWAS studies, NIH Common Fund, etc.)

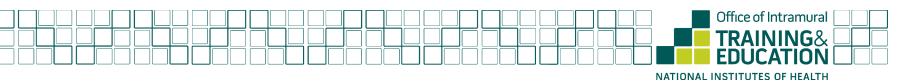
http://www.grants.nih.gov/grants/funding/ funding\_program.htm#Trans



### **Know What the NIH Funds**

Use the RePORTER at <a href="http://report.nih.gov/index.aspx">http://report.nih.gov/index.aspx</a>





### Study Sections and Peer Review

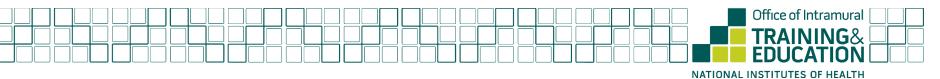
WATCH!

http://www.youtube.com/watch?v=fBDxI6I4dOA



# How Applications Are Assigned To Institutes and Study Sections

- Based on input from you -- in a cover letter
- Based on past review history of the application (if any)
- Based on the research area
- Depending on the type of application (R01, F32, K series, etc.)



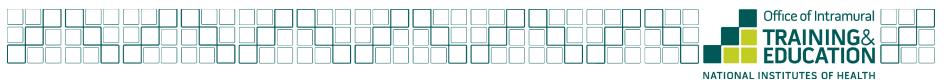
### Who Serves on Study Section

- University faculty, NIH intramural investigators, and industry scientists
- SRO works carefully to recruit diverse participants
- Basic/Clinical ranges from 60/40 to 40/60
- Some members are permanent members, serving ~4 years;
   others are ad hoc members participating for one meeting



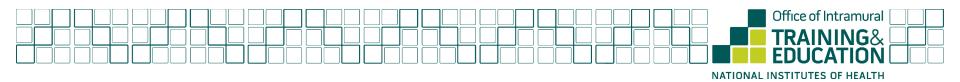
### Study Sections and Reviewers

- Typically review 70-120 applications
- Applications are assigned a primary and secondary reviewer; most are also assigned one or two readers
- Reviewers are assigned 9 12 applications
- Reviewers write critiques for the applications on which they have primary or secondary responsibility
- You cannot contact reviewers, before or after review



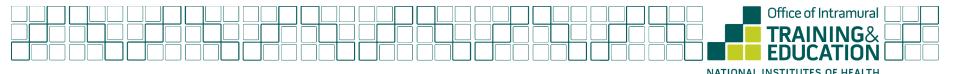
### What Happens at Study Section

- Assigned reviewers state their preliminary scores
- Primary reviewer introduces the application; discusses strengths and weaknesses
- Secondary reviewers focus on differences & additions
- Other reviewers share their thoughts
- Committee members join the discussion
- Assigned reviewers restate their scores
- All reviewers vote
- All reviewers weigh in on animal usage, human subject concerns, and budgetary issues
- Primary and secondary reviewers amend their written reviews which are submitted to the SRO for processing



# What Reviewers Evaluate for Research Grants

- Overall Impact
- "Core" Criteria
  - Significance
  - Investigators
  - Innovation
  - Approach
  - Environment
- Additional Issues (e.g. Human Subjects Protections)



# What Reviewers Evaluate for Training and Career Grants

- Overall Impact
- Candidate
- Career Development Plan
- Research Plan
- Mentor(s), Consultant(s), Collaborator(s)
- Environment and Institutional Commitment
- Other criteria include: RCR plans, humans/animals, etc.



### The Scoring System

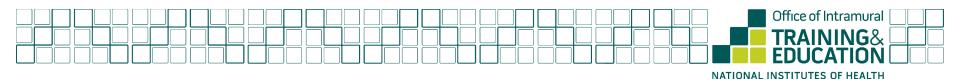
"Old" System	"New" System
Priority Score Range: 100-500	Overall Impact Score Range: 10-90 (integers only)
	Criterion Scores: 1-9 (integers only)

- 1 is still the best
- Overall impact score need not be mathematically related to criterion scores. Reviewers weight the criterion scores as they believe appropriate in assigning overall impact score.



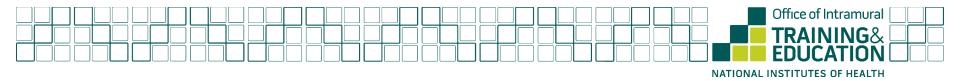
### Scoring Guidance

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong; essentially no weaknesses
2	Outstanding	Extremely strong; negligible weaknesses
3	Excellent	Very strong; only some minor weaknesses
4	Very Good	Strong but numerous minor weaknesses
5	Good	Strong but at least one moderate weakness
6	Satisfactory	Some strengths; some moderate weaknesses
7	Fair	Some strengths but at least one major weakness
8	Marginal	A few strengths; a few major weaknesses
9	Poor	Very few strengths; numerous major weaknesses



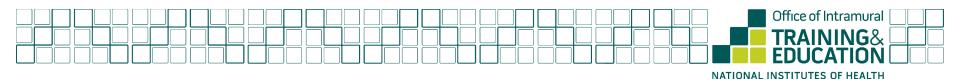
### What the Summary Statement Looks Like

- Reviewers use a structured template
- Reviewers provide bulleted comments for:
  - Overall strengths & weaknesses
  - Strengths & weaknesses of each core criterion
  - Comments on Other Review Considerations
- Additional comments ("advice" to applicant)
- Goal: increase transparency of review process and to improve feedback provided to applicants.



### What about Not Discussed Applications?

- Applications that are not discussed by the review panel:
  - Are generally those in the lower half
  - Do not receive an overall impact score
  - Receive summary statements that include the written critiques and criterion scores from the assigned reviewers but do not include an overall impact score

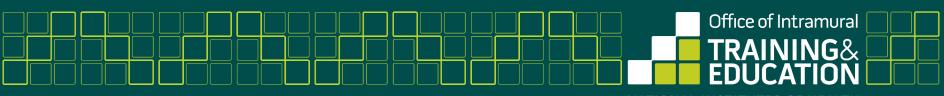


### The Review process is a 2 Level System

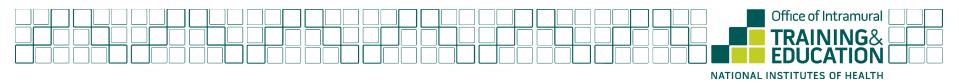
- 1st Level: Initial Scientific Peer Review
  - Independent, outside reviewers
  - Evaluates the scientific merit and significance
  - Does NOT make funding decisions
- 2nd Level: IC National Advisory Council or Board
  - Evaluates quality of initial peer review
  - Makes recommendations to Institute staff on funding
  - Evaluates program priorities and relevance

## Strategies for Success

Dr. Sharon L. Milgram, Director NIH OITE milgrams@od.nih.gov



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### The Psychology of Grant Review

- Reviewers are:
  - Over-committed, over-worked and tired
  - Inherently skeptical and critical
  - Often only peripherally interested in your work
- Make their job easier with:
  - Well-organized, clearly written prose
  - Lots of section headings and breaks in the writing
  - Repetition of important points at several places in the application
  - Well designed flow diagrams, charts, figures
- And avoid irritating them by:
  - Exceeding page limits, using small fonts and narrow margins
  - Putting information in the wrong section
  - Omitting or mislabeling references/figures
  - Submitting a sloppy application with a lot of typographical errors



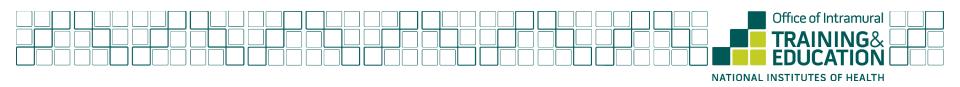
### Be Aware of Timing

Receipt Dates Meetings Council Start Date

1 Jan Feb Mar Apr May June July Aug Sept Oct Nov Dec

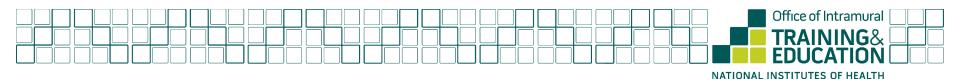
2 May June July Aug Sept Oct Nov Dec Jan Feb Mar Apr

3 Sept Oct Nov Dec Jan Feb Mar Apr May June July Aug



### Getting Started: Administration Issues

- Download and carefully read all instructions and deadlines (Parent FOA, RFA, etc.)
- Make sure you are registered for government internet based application and award systems, particularly eRA Commons
- Talk with lab/department/IC administrators about budgeting, all required approvals, and routing procedures
- Begin all required approvals well in advance of the deadline; 3 months is not unreasonable at the beginning of your career
- Contact collaborators and arrange for letters as needed



### Getting Started: Science Issues

- Read the literature broadly not deeply; save important papers for a deeper read later
- Engage your lab, mentors and collaborators in the brainstorming process
- Find outside experts to talk with but go prepared
- Begin early to define, organize and plan the content
- NOTE: Early means ~6 months before the deadline



### Elements of NIH Research Grants

- Cover Letter
- Title Pages
- Abstract
- Budget with Justifications
- Biosketch(es) of Investigators
- Resources and Facilities
- Introduction (resubmissions/revisions only!)
- Specific Aims (1 page)
- Research Strategy (6-12)
- References
- Human subjects, animals, and other assurances



### The Cover Letter

- To suggest IC for funding or study section for review
  - Be sure and discuss with PO/SRO in advance
  - Mention their name in the cover letter
- To suggest the types of expertise that would be needed to review your application
  - Requests for specific reviewers will be ignored
- Can request that one or two specific individuals not be used as reviewers
  - Be prepared to discuss your reasons with the SRO



# Excellent Resources for Writing Your Application

- Table of page limits: <a href="http://grants.nih.gov/grants/forms">http://grants.nih.gov/grants/forms</a> page limits.htm
- Examples of successful applications from NIAID <a href="http://www.niaid.nih.gov/researchfunding/grant/Pages/appsamples.aspx#rpindex">http://www.niaid.nih.gov/researchfunding/grant/Pages/appsamples.aspx#rpindex</a>



### Specific Aims

- Provides an overview of the details tells what your proposal is about, and how you will get there
  - start with 1 2 paragraph general overview
  - then list AIMS, each clearly defined
  - end with a brief statement of what you will learn if successful
- The reader must finish this section convinced that the proposed research is significant <u>and</u> that you have a feasible approach
- The aims should be clearly and concisely stated; many also include sub-aims
- Typically 2 4 related aims. Later aims should NOT totally depend on the success of previous aims



### Example 1 (AIM 1 of 3)

# **AIM 1. Study the role of the CFTR-FLN interaction in CFTR folding and ER export**: We find that FLN directly associates with residues 1-25 of CFTR and that Ser13 is required for this interaction. We further find that S13F CFTR is abnormally processed when expressed in mammalian cell lines, suggesting that the association with FLN plays a role in the maturation or stability of CFTR. Thus we will:

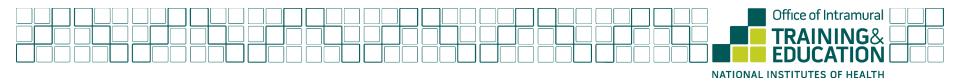
- 1A. Complete the biochemical characterization of the CFTR-FLN interaction
- 1B. Compare the biosynthesis and trafficking of WT and S13F CFTR
- 1C. Determine the role of FLN in the regulation of CFTR biogenesis and trafficking in FLN-null cells



# Important Point

The specific aims page is your hook

Make it as perfect as possible



## Research Strategy Section

- Significance
- Innovation
- Approach
  - Preliminary studies/progress report
  - Experimental design and method



# As You Write, Keep This In Mind

- Your grant application will likely have several types of assigned reviewers:
  - An expert in the field
  - Someone who is smart but knows little about your field
- Therefore, your application must appeal to both audiences
- It is your goal to get people excited about your research
  - Let your enthusiasm for your research be reflected in your proposal.
  - ☐ If you are not enthusiastic when writing your proposal, it is unlikely the reviewers will see anything different



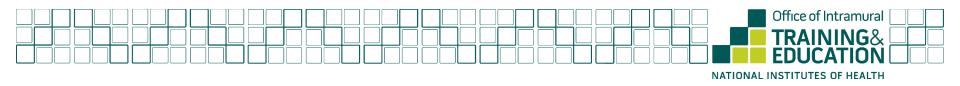
#### Significance

- You must clearly state the importance of the proposed research
- Write looking both backward and forward
  - How we got "here" and where we need to be
- Important to point out any controversies and discrepancies that your work will address
- Should be appropriately referenced with an honest and balanced discussion of the field



# Research Strategy - Innovation

- Will this effort shift current research or clinical practice paradigms?
- Is the proposed work new? Creative? Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions(s) to be developed.
- How will the results direct/inform future research?
- Will success improve the "State-of-the-art", or establish new research directions?
- Remember that faked innovation will get you in trouble, so be clear, but do not "make something of nothing"



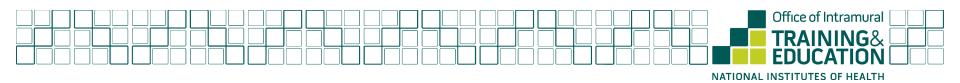
# Changes in review were designed to place more focus on <u>impact</u> and less on details of approach

Impact combines significance and feasibility



#### Feasibility = Preliminary Data

- To show that you can do what you say you are going to do
- To generate excitement and enthusiasm for the proposed studies
- To show you are a careful scientist who understands the value of controls and does not over-interpret data
- Typically several figures with clear legends; figures should be large enough for reviewers to easily read
- Do not assume the reviewers will go to look at your publications; give them everything they need to review the grant



#### Research Approach

- Organized by specific aims
- Include an overview of approaches and the rationale for experiments
- Define controls (positive and negative) for all experimental approaches
- Show you have thought through issues of feasibility, sample size, data analysis, etc.
- Include a discussion of expected outcomes and data interpretation
- Include a discussion of potential problems, and alternate approaches



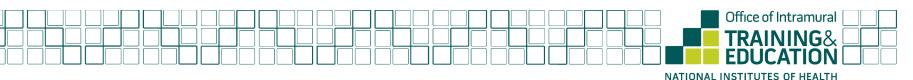
# Strong Research Plans:

- Explicitly state the rationale for the proposed studies
- Never assume reviewers will intrinsically appreciate or understand what you intend
- Use flow diagrams for overview, and for complex experiments and protocols
- Include well-designed, easy to follow tables and figures
- Address priorities if patients, reagents or resources will be limited
- Include a discussion of how the data will be analyzed and interpreted
- Include realistic discussions of pitfalls and provide alternate approaches



#### Sections of a K Grant

SECTION	PAGE LIMIT
Introduction to revised application (if resubmission)	1
Specific Aims	1
Candidate Information including: a) Background; b) Career Goals/ Objectives; and c) Career Development Plan	12 TOTAL
Research Strategy including: a) Significance; b) Innovation and c) Approach	
Training in the Responsible Conduct of Research	1
Mentoring Plan (when required)	6
Statements by Mentor, Co-Mentors, Consultants, Contributors	6
Description of Institutional Environment	1
Institutional Commitment to Candidate's Research Career Development	1
Biographical Sketch	4



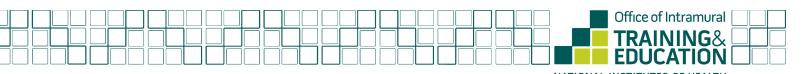
### Candidate Background

- Explain where you have been and how it relates to where you are going (Career goals and Objectives)
- Highlight:
  - Your prior training and how it relates to your objectives and long-term career plans
  - Explain why you chose the mentors you chose, the projects you focused on, and the activities you engaged in
  - Detail your professional responsibilities at NIH and elsewhere and how they relate to your proposed K activities
- Clearly explain your path toward becoming an independent investigator
  - If your research focus has changed direction, give the reasons and explain the progression



#### Career Goals and Objectives

- What do you want to do in your future career
  - In your research
  - And beyond; for example in the areas of teaching, mentoring, field work, clinical work, etc)
- Discuss your plans to apply for subsequent grant support and briefly describe how the K Award will facilitate that process
- It is important to justify the award and how it will enable you to develop or expand your research career



## Career Development Plan

- Describe new/enhanced research skills and knowledge you will acquire
- Described new/enhanced professional skills and knowledge you will acquire
- For mentored awards include a clear discussion of your mentor(s); how/when you will interact with them and what each will provide during your training
  - Although some K awards are not mentored awards (ie NIAID K22) a brief explanation of mentoring relationships often strengthens the application
- Discuss each activity, include a percentage of time by year, explain how activity relates to the proposed research and the career development plan



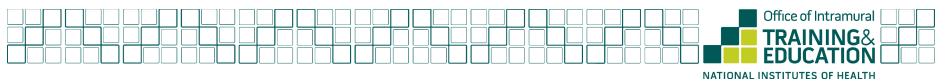
#### What To Cover In A Career Plan

- Additional technical training, not incremental advances in what you already know
- Didactic training
  - Depends on your educational level and background
  - Traditional and non-traditional ways
- Professional training
  - In anything you will need to be successful as an independent scientist
  - Including communication, mentoring, teaching, management, and leadership skills
- Job Search information
  - Who will help and when
  - Availability of institutional resources



#### **Strong Career Plans:**

- Goes beyond the "standard stuff"
  - Standard is lab meetings, journal clubs, attending the obvious National/International meeting
- Are based on your career goals, not someone else's or on a standard institutional template
- Demonstrate that there is a meaningful interaction between the mentor(s) and the mentee
  - Meaningful letters and specifics help
- Involves a mentoring team when appropriate
  - Especially important if you have an inexperienced mentors
  - □ When research diverges from mentor's expertise
  - □ When career goals are outside the mentor's expertise
- Show some evidence that you mean what you say



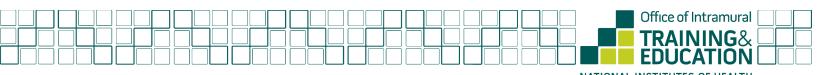
#### Common Criticisms – K and R grants

- Rationale for hypothesis or methods not sound
- Models over-hyped as relevant to the human situation
- Diffuse, unfocused or superficial examination of the field
- Unexciting science an incremental advance for the field
- Mediocre preliminary data that are over-interpreted
- Lack of experience in required methodologies
- Unrealistic amount of work
- Lack of sufficient experimental detail
- Too many irrelevant experimental details
- Insufficient discussion of pitfalls and alternate approaches
- Lack of knowledge of published work
- Lacks evidence that the fellow and mentor worked together
- Lack of detail in the training plan; letters from mentors lack depth



#### What Reviewers Really Say

- This is the first of three very long aims that could make its own proposal. The subaims just go on and on.
- An important question and an elegant approach; however there is no discussion of how many targets are expected, and most importantly, what criteria will be used to select which targets to pursue.
- The role of these senior scientists needs to be defined.
- This is a horizontal contribution to the field.
- The investigator does not pay sufficient attention to feasibility issues, including the enrollment of research subjects and careful attention to inclusion issues.
- Insufficient information is given to indicate how the CART analysis will be implemented, and no discussion of power analysis is given. These omissions are particularly unfortunate.



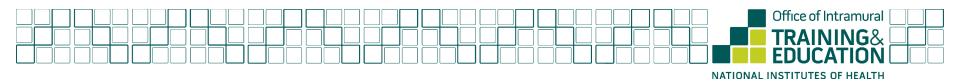
#### How to Approach a Negative Review

- Give yourself the time and space to feel sad and angry, but appreciate that your colleagues, students, lab members are watching
- Avoid calling or writing your program officer until you have calmed down
- Then read the reviewer's comments CAREFULLY
- You will need to decide whether or not the reviewers show any enthusiasm for your application.
- Talk with:
  - A senior scientist with experience reading critiques
  - Your program officer



#### **Amended Applications**

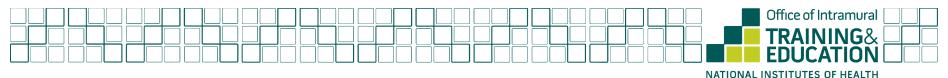
- Can submit <u>one</u> amended application
- Must respond to reviewers' criticisms
  - Do not have to agree or make the suggested changes, but must respond to the comments
  - Do not attack the reviewers' competence, abilities, etc. This will only hurt your cause.
- No guarantees that amended application will score better than previous submission
  - Different reviewers
  - Different panel of applications



#### An example – Absolute Agreement

Reviewer 1 accurately pointed out that we had not sufficiently discussed the detergents used to prepare cell lysates for our assays. We now expanded this discussion in AIM 3 of the revised application.

Reviewer 2 pointed out that we lacked a clear way to address the relevance of these protein interactions in an animal model. There are no universally accepted animal models for CF lung disease, but we now include studies in mouse tissues and/or well-differentiated human primary airway epithelial (WD-PAE) cell cultures to further explore the physiological relevance of the interactions we identify.



#### An Example - Graciously Disagreeing

We wholeheartedly agree with Reviewer 2 that unfocused research can indeed lead to "a quagmire of proteins". However, we have several strategies in place to ensure that we do not go down such a path. Specifically, ....... As proof of principle, our progress since June 2004 clearly indicates that we can rapidly identify important proteins for further analysis. Therefore we have retained the protein interactions screens described in AIM 3 of the original application.



"Simple can be harder than complex. You have to work hard to get your thinking clean to make it simple. But it's worth it in the end, because once you get there, you can move mountains."



#### It's About More Than The Science

#### Observation I:

 Strong writing can not compensate for bad ideas, but weak writing easily ruins good ideas

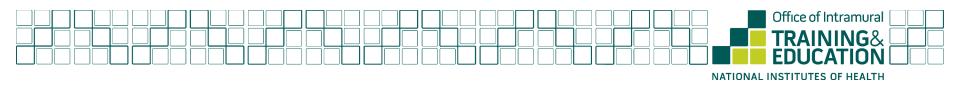
#### Observation II:

 You can learn to write well; find outstanding resources as early as possible



#### Conclusion

- Only some of the deserving applications can be funded
- Maximize your chances for success by
  - Planning ahead
  - Remembering your target audiences
  - Showing the reviewers that you have thought deeply about your project
  - Preparing a reader-friendly application
  - Remaining optimistic, and letting your enthusiasm for your science come through



#### Helpful Resources

- NIH Home page <a href="http://www.nih.gov/">http://www.nih.gov/</a>
- NIH Grant Application Basics (Includes guides, tips, and tutorials) <a href="http://grants.nih.gov/grants/grant-basics.htm">http://grants.nih.gov/grants/grant-basics.htm</a>
- Information on Study Sections <a href="http://cms.csr.nih.gov/">http://cms.csr.nih.gov/</a>
- For NIH Intramural fellows:
  - Check with your Intramural IC training director or other IC contact for IC-specific funding opportunities, grant writing programs and other information for intramural fellows
  - Visit the OITE web site for information on foundation and government grants that you are eligible to apply for
- Questions? Want to talk? Email me at milgrams@od.nih.gov